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The attached documents are exact copies of the European patent application described on the following page, as originally filed.

Les documents fixés à cette attestation sont conformes à la version initialement déposée de la demande de brevet européen spécifiée à la page suivante.

Patentanmeldung Nr. Patent application No. Demande de brevet n°

02102732.1

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Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
p.o.

R C van Dijk

DEN HAAG, DEN
THE HAGUE, 02/02/04
LA HAYE, LE

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Blatt 2 der Bescheinigung
Sheet 2 of the certificate
Page 2 de l'attestation

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Soft surgical tissue mesh

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The applicant's name at the time of filing of the application was as follows:
DSM N.V.

The registration of the change has taken affect on 10 July 2003 (10.07.2003)

SOFT SURGICAL TISSUE MESH

The present invention relates to a surgical mesh and, more particularly, to a soft and flexible surgical mesh.

Using surgical mesh for the repair and restoration of living tissue is well known. For example, in US 6,042,592 a surgical mesh is described, which is used to support and/or reinforce a damaged or weakened portion of the body. US 6,042,592 further describes that, a mesh must additionally be sufficiently porous to allow for growth of tissue through the graft after implantation. A healing tissue generally grows through porous openings in the implanted mesh, thereby assimilating the mesh and adding structural integrity to the tissue.

U.S. Pat. No. 3,054,406 discloses another example of a surgical mesh used for repair and restoration of living tissue. The surgical mesh described therein may be woven from either monofilament or multifilament polyethylene yarns. The mesh has limited pliability when formed of monofilament yarns, and may be prone to harboring of infectious matter when formed of multifilament yarns.

A surgical mesh has been extremely useful in the field of repairing soft tissue such as during a hernia repair operation. Groin herniorrhaphy is among the oldest and most common surgical procedures performed. Unfortunately, the average operative result is beset by a period of discomfort with resultant disability. Techniques have been developed, such as laparoscopic herniorrhaphy, with the intent to reduce morbidity and recurrence rates. Most trials, however, have noted only a moderate improvement in the pain and disability associated with the procedure. Further, the added cost of equipment, the need for general anesthesia, and the additional operating room time required for laparoscopic herniorrhaphy indicates that this procedure is less than ideal. There continues to be a need for a procedure that can effectively address all the considerations of cost, disability, and hernia recurrence for patients with an inguinal hernia.

While the placement of a prosthetic mesh in the properitoneal space is currently performed with either a laparoscopic or an open technique, it is desirable to perform the procedure through even less invasive means. One such means contemplated involves the use of needles to deliver the mesh into the peritoneal cavity. Delivery of mesh by means of a needle, however, has heretofore hardly been possible in part due to the unavailability of a mesh which is thin enough to be passed through

the cannula of a needle, yet of sufficient tenacity and flexibility to adequately serve its intended purpose.

There is therefore a need for a soft tissue surgical mesh which can be made having a thickness that allows the mesh to be rolled or folded and thereafter inserted into the cannula of a needle for deployment in the body and which exhibits both the soft and pliable characteristics of a mesh produced from multifilament yarns and the infection resistance of a mesh produced from monofilament yarns. In order to provide a mesh with a low thickness, the yarns of which the mesh is made should have a high tenacity. However yarns with a high tenacity generally have a too low flexibility for surgical meshes.

It is the aim of the invention to provide a mesh, which combines flexibility with a sufficient tenacity to obtain a thinner mesh than the known meshes.

According to the invention this is obtained by a mesh with polyethylene yarns having a tenacity of more than 10 cN/dTecx, the yarn of which consisting of a polyethylene with a relative viscosity of more than 5 dl/g.

Herewith a mesh can be obtained which is both thin and flexible enough for the surgical use mentioned above.

A surgical mesh can be produced by knitting, weaving, braiding, or otherwise forming a plurality of yarns into a mesh. Preferably the mesh of the invention is knitted.

The mesh comprises polyethylene yarns having a tenacity of more than 10 cN/dTex, preferably more than 20 cN/dTex and consist of a polyethylene with an relative viscosity of more than 5 dl/g, measured at a concentration of 0,05% in decalin at 135°C according to ASTM D 4020. Preferably the relative viscosity of the polyethylene is more than 10 dl/g. An advantage of a mesh comprising a yarn made from polyethylene with a relative viscosity of more than 10 dl/g is the high fatigue strength of such a mesh.

The thickness of the yarn may vary between wide ranges. A suitable thickness for the yarns in the mesh of the invention however is between 10 and 500 denier.

A mesh can be produced with monofilament or multifilament yarns. Surgical mesh formed of monofilament yarn provides satisfactory reinforcement ability, but is generally stiff and has limited pliability. In contrast, surgical mesh formed of multifilament yarn is soft and flexible in comparison to mesh formed of monofilament yarn. However, mesh formed of multifilament yarn may tend to harbor infectious matter

such as bacteria. Particularly, the small void areas or interstitial spaces between the filaments of a multifilament yarns may promote the breeding of such bacteria. To date, surgeons typically prefer the monofilament design because of its improved resistance to harboring of infectious matter. As a result of this choice, surgeons must forego the advantages associated with multifilament yarns.

In a special embodiment of the invention the yarns are composite yarns comprising a sheath and a core, such that the weight ratio between sheath and core is below 3:1. Such a composite yarn combines the advantages of a flexible multifilament yarn with a yarn being less prone to harboring of infectious matter.

In one preferred embodiment of the present invention, a medicinal drug (e.g., an antibiotic) is incorporated into the yarns.

The invention further relates to a method of producing a surgical soft and flexible soft tissue mesh comprising polyethylene yarns, wherein the yarns comprise filaments made by:

a) spinning at least one filament from a solution of polyethylene with a relative viscosity of more than 5 dl/g in a solvent;
b) cooling the filament obtained to form a gel filament;
c) removing at least partly the solvent from the gel filament; and
d) drawing the filament in at least one drawing step before, during or after removing solvent.

Such a spinning process is generally referred to as a gel spinning process. Gel spinning of polyethylene with a relative viscosity of more than 5 dl/g (ultra high molecular weight polyethylene; UHMwPE) has been described in various publications, including EP 0205960 A, EP 0213208 A1, US 4413110, WO 01/73173 A1, and Advanced Fiber Spinning Technology, Ed. T. Nakajima, Woodhead Publ. Ltd (1994), ISBN 1-855-73182-7, and references cited therein.such that the tenacity is more than 10 cN/dTex.

The invention further relates to a preferred method, wherein the yarns are subjected to a heat treatment, optionally in the presence of a second solvent for polyethylene, in which a composite yarn is formed comprising a sheath and a core, such that the weight ratio between sheath and core is below 3:1. In this process the yarns may be in the form of a braided, twisted or intermingled bundles of filaments.

The conditions, like temperature and residence time of the process according to the preferred method of the invention are selected to be high, respectively long enough to soften the filaments and allow them to combine at least at the surface

of the yarn such that a sheath is formed. Conditions useful for the surface combining process include a temperature or series of oven temperatures within the melting point range of the filament polymer that allows for forming a core-sheath composition during the exposure period. The temperature at which the preferred process is carried out is preferably within the range from about 150° C up to about 157° C for gel spun polyethylene yarns exhibiting a relaxed melting point range of 138° to about 162° C. at a 20° C./minute scan rate and having a relative viscosity of more than 5 dl/g. Residence times during which the line is exposed to the oven temperature are within the range from about 6 seconds to about 150 seconds. The weight ratio between sheath and core can be adjusted by increasing or decreasing the oven temperature, increasing or decreasing the residence time, or by applying a pressure to the surface of the yarns.

Optionally a second solvent can be applied to the surface of the yarn, to enhance the process of making a composite yarn. Such second solvent may include mineral oil (e.g., heat transfer grade mineral oil with an average molecular weight of 250-700) paraffin oil, and vegetable oil (e.g., coconut oil), or any other solvent for polyethylene, such as decalin, toluene or hexane. Contact between the tread or yarn and the second solvent can be performed under ambient conditions (e.g., 20°-25° C.) or under elevated temperatures (e.g., up to about 100-150° C. or higher). Mineral oil acts as a plasticiser that enhances the efficiency of the process permitting the process for making the composite fiber to be performed at lower temperatures.

Optionally the first and the second solvent are the same.,

The invention also relates to a method of producing a surgical soft and flexible soft tissue mesh wherein the method further comprises a step of incorporating a medical drug into the yarns.

This can be done by adding the medical drug to the first solvent wherein the polyethylene is dissolved. Another way to incorporate a medical drug into the yarns is to add the medical drug to the second solvent.

In order to obtain a more stable mesh structure the yarns of the mesh can be heat setted. This can be done by heating the mesh under constant strain at a temperature between the melting temperature of the polyethylene and a temperature which is not more than 20 below the melting temperature.

CLAIMS

1. Surgical soft and flexible soft tissue mesh comprising polyethylene yarns, characterized in that the polyethylene yarns have a tenacity of more than 10 cN/dTecx and consist of a polyethylene with an relative viscosity of more than 5 dl/g.
2. Mesh according to claim 1 wherein the mesh is knitted.
3. Mesh according to claim 1 or claim 2, wherein the yarns are composite yarns comprising a sheath and a core, such that the weight ratio between sheath and core is below 3:1.
4. Mesh according to any of claims 1-3 wherein the yarn comprises a medical drug.
5. Method of producing a surgical soft and flexible soft tissue mesh comprising polyethylene yarns, characterized in that the yarns comprise filaments made by:
   a) spinning at least one filament from a solution of polyethylene with a relative viscosity of more than 5 dl/g in a solvent;
   b) cooling the filament obtained to form a gel filament;
   c) removing at least partly the solvent from the gel filament; and
   d) drawing the filament in at least one drawing step before, during or after removing solvent.
6. Method according to claim 5, wherein the yarns are subjected to a heat treatment optionally in the presence of a second solvent for polyethylene in which a composite yarn is formed comprising a sheath and a core, such that the weight ratio between sheath and core is below 3:1.
7. Method according to 5 or 6, wherein the method further comprises a step of incorporating a medical drug into the yarns by adding the drug to the first or the second solvent.
8. Method according to any of claims 5- 7 wherein the mesh is heat setted under constant strain at a temperature between the melting temperature of the polyethylene and a temperature which is not more than 20 below the melting temperature.

ABSTRACT

The invention relates to a surgical soft and flexible soft tissue mesh comprising polyethylene yarns, wherein the polyethylene yarns have a tenacity of more than 10 cN/dTecx and consist of a polyethylene with an relative viscosity of more than 5 dl/g.

A further aspect of the invention is a method of producing a surgical soft and flexible soft tissue mesh comprising polyethylene yarns, wherein the yarns comprise filaments made by:

a) spinning at least one filament from a solution of polyethylene with a relative viscosity of more than 5 dl/g in a solvent;
b) cooling the filament obtained to form a gel filament
c) removing at least partly the solvent from the gel filament; and
d) drawing the filament in at least one drawing step before, during or after removing solvent.